

b.) REMARKS

Claims 1 and 6 have been amended in order to recite the present invention with the specificity required by statute. Additionally, new Claim 8 is presented in order to more specifically recite various preferred embodiments of the present invention. Support for this new claim may be found in Examples 9-13, 15, 16, 18-28, 30, 32-34, 41-46 and 48-50. Accordingly, no new matter has been added. Claim 2 has been cancelled, as its subject matter is now incorporated in Claim 1.

In the Office Action dated December 8, 2006, the Examiner rejected claims 1-7 under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. More specifically, the Examiner asserted that the use of the words "derivative" and "general" were vague and suggested "derivative" be replaced with -- compound-- and that "general" be deleted. Further, various informalities in the capitalization and punctuation of claim 1 were pointed out in the rejection. Finally, the Examiner noted that claim 6 was vague because it did not positively recite the addition of a pharmaceutical carrier. The applicants have adopted all of the Examiner's suggestions and corrected the informalities in the amendment to claim 1. Applicants therefore believe the section 112, second paragraph rejection has been overcome and withdrawal of this rejection is respectfully requested.

An obviousness-type double patenting rejection has been entered by the Examiner. Claims 1-7 have been rejected on this basis in view of claims 1-6 in commonly owned U.S. Patent 6,642,224. Additionally, a provisional obviousness-type double patenting rejection of claims 1-7 has been entered based on the claims found in co-pending application 10/399,625.

Applicants will submit a Terminal Disclaimer to remove the double patenting rejection based on U.S. Patent 6,642,224. Submitting the Terminal Disclaimer will remove this basis for rejection.

Because there have been no claims indicated as allowable in either the present case or in the co-pending application 10/399,625, applicants cannot yet determine whether filing a Terminal Disclaimer is warranted, and therefore ask that the provisional double patenting rejection be held in abeyance until allowable subject matter is found in at least one of these pending applications.

The Examiner also rejected claims 1, 3, 4, 6 and 7 under section 102(e) as anticipated over the published application Herron, U.S. Patent Application Publication No. 2004/0097491 ("Herron '491"). Claims 1-7 were rejected as obvious under section 103 as unpatentable over this same Herron reference. The Examiner asserts that the generic structures of Herron encompass the claimed compounds for the same use.

Claims 1-7 have also been rejected under section 103 as unpatentable over Herron, U.S. Patent Application Publication No. 2004/0058989 ("Herron '989"). The Examiner again alleges that the generic structure found in this reference encompasses the applicants' claimed compounds.

Applicants respectfully traverse the prior art rejections.

Section 102(e)

The Examiner has rejected claims 1, 3, 4, 6 and 7 as unpatentable under section 102(e) over Herron '491. Applicants have now amended the claims so that the limitation of claim 2, which the Examiner did not find anticipated, has been inserted into generic claim 1.

In determining whether a compound is new, the compound must not be described in a single prior art reference. The prior art does not disclose any of applicants' claimed compounds. Applicants claimed compounds all require a hydroxyl substituted phenyl ring which is attached via NHCO and CONH linkages to other ring systems. Since the prior art does not show this feature, the prior art does not describe the subject matter of their claims under section 102.

Accordingly, since anticipation requires that each and every element of the claimed invention be found in the reference and arranged as in the claims, applicants respectfully submit that the rejection based on section 102(e) has been overcome due to the amendment to claim 1, and therefore should be withdrawn.

With respect to the section 103 rejections, applicants assert that both Herron references fail to meet the criteria necessary to establish obviousness. To establish a *prima facie* case of obviousness, the Examiner must show that there is a structural similarity between the claimed compounds and those of the prior art, in addition to providing a motivation, found in the references or demonstrably within the skill of the art, to modify the reference teachings. There must also be a reasonable expectation of success and the prior art reference must teach or suggest all of the limitations.

Cases addressing the issue of structural similarity demonstrate that the differences between the claimed compounds and those of the prior art must be relatively small to establish structural similarity. Common relationships between the reference and claimed compounds found to create *prima facie* obviousness are stereoisomers, adjacent homologs and structural isomers.

Under this standard, there is no structural similarity between the compounds taught by either Herron reference and those claimed by applicants. Again, neither reference teaches the importance of having a hydroxyl substituted phenyl ring as the central ring. Indeed, not a single Example of these two references (Examples 1-85 and P1-P31 in Herron '491, and Examples P1-P3 and 1-25 in Herron '989) shows a hydroxyl substituted phenyl ring. Moreover, there is no teaching that it is even necessary to have a phenyl ring. Several examples of each reference employ a nitrogen containing heteroaryl ring instead of the phenyl ring. (See, e.g., Examples P20 and Examples 21, 46, 55, 74, 84 and 85 of Herron '491 and Examples 8 and 16 of Herron '989.) In such circumstances, it is not possible to say that there is structural similarity between the claimed compounds and the compounds found in the two references. For this reason alone, the section 103 rejection should be withdrawn.

Additionally, however, there is no motivation or basis present to make the selection of a hydroxyl substituted phenyl ring in the prior art. Biological data is totally absent from the two Herron references, providing one skilled in the art with no rationale for selecting any of the substituents or any of the compounds found in the references for further study or modification. There is no other basis to lead one of skill in the art to make the particular substitution that would be required to arrive at applicants' invention, other than applicants' own disclosure. In such a situation, it is plain that yet another important element to establishing obviousness of chemical compounds has not been met.

The absence of biological data in the two Herron references also impacts the third criteria, that there be a reasonable expectation of success. There can be no such expectation because there is no reason provided to select one modification to the Herron compounds over another.

Therefore, since the compounds found in the prior art Herron published patent applications are not structurally similar to the compounds claimed in the present application and because there is no basis or motivation for one of ordinary skill in the art to modify any of the Herron compounds to arrive at applicants' invention, and there is no reasonable expectation of success, the section 103 rejections based on Herron '491 and Herron '989 should be withdrawn.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1 and 3-8 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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